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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,314	10/11/2007	Maurice Bourlion	BDM-06-1214	6499

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ONE LIBERTY PLACE
1650 MARKET ST, SUITE 4900
PHILADELPHIA, PA 19103

EXAMINER

SMITH, FANGEMONIQUE A

ART UNIT	PAPER NUMBER
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3736

MAIL DATE	DELIVERY MODE
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06/09/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/589,314	Applicant(s) BOURLION ET AL.	
	Examiner Fangemonique Smith	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 17-29 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 August 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/11/06</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "2" has been used to designate both an electrode in Figures 1A, 1B, 2, and 6, and the instrument in Figure 7. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

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3. The drawings are objected to under 37 CFR 1.83(a) because they fail to show the drilling instrument (1) as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

4. Claim 17 is objected to because of the following informalities:
- a. At line 5 of claim 17, it is suggested to modify the limitation “the electrodes” to read -- the at least two electrodes -- to maintain consistency in claim terminology.
- Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 17-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 17 recites the limitation "the first electrode" in line 6. Prior to this recitation, at least two electrodes were introduced. It is unclear whether the first electrode disclosed by this limitation refers to one of the at least two electrodes previously disclosed, or if the limitation intends to introduce another electrode in addition to the at least two electrodes previously disclosed, rendering the claim indefinite. As a result, claim 17 is rejected. Upon rejection of claim 17, all claims depending from claim 17 are also rejected.

8. Claim 17 recites the limitation "the second electrode" in line 7. Prior to this recitation, at least two electrodes were introduced. It is unclear whether the second electrode disclosed by this limitation refers to one of the at least two electrodes previously disclosed, or if the limitation intends to introduce another electrode in addition to the at least two electrodes previously disclosed, rendering the claim indefinite. As a result, claim 17 is rejected. Upon rejection of claim 17, all claims depending from claim 17 are also rejected.

9. Claims 18 and 19 both recite the limitation "the two electrodes coinciding with the distal surface" in lines 1 and 2. Prior to this recitation, a first electrode which coincided with a distal surface of the penetration instrument was introduced. It is unclear to which two electrodes this

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limitation refers since only one electrode was previously disclosed as coinciding with the distal surface, rendering the claim indefinite. Upon rejection of claims 18 and 19, all claims depending from claims 18 and 19 are also rejected.

10. Claims 18 and 19 both recite the limitation "the electrodes " in line 2. Prior to this recitation, a first electrode which coincided with a distal surface of the penetration instrument, a second electrode which coincided with a lateral surface of the penetration instrument and at least two electrodes were all introduced. It is unclear to which electrodes this limitation refers, rendering the claim indefinite. Upon rejection of claims 18 and 19, all claims depending from claims 18 and 19 are also rejected.

11. Claim 20 recites the limitation "the electrode" in line 1. Prior to this recitation, a first electrode which coincided with a distal surface of the penetration instrument, a second electrode which coincided with a lateral surface of the penetration instrument and at least two electrodes were all introduced. It is unclear to which electrode this limitation refers, rendering the claim indefinite. Upon rejection of claims 20, all claim depending from claim 20 is also rejected.

12. Claim 21 recites the limitation "one main electrode" in line 1. Prior to this recitation, at least two electrodes, a first electrode and a second electrode were all introduced. It is unclear to which electrode this limitation refers, or if the limitation intends to introduce another electrode, rendering the claim indefinite. Upon rejection of claim 21, all claims depending from claim 21 are also rejected.

13. Claim 21 recites the limitation "a distal surface of the penetrating instrument" in line 2. Prior to this recitation, a distal surface of the penetrating instrument was introduced. It is unclear whether the distal surface of the penetrating instrument disclosed by this limitation refers to the

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distal surface of the penetrating instrument previously disclosed, or if the limitation intends to introduce another distal surface of the penetrating instrument, rendering the claim indefinite. As a result, claim 21 is rejected. Upon rejection of claim 21, all claims depending from claim 21 are also rejected.

14. Claim 22 recites the limitation "a first electrode" in line 1. Prior to this recitation, a first electrode has been introduced. It is unclear if the limitation refers to the first electrode previously introduced, or if the limitation intends to introduce another first electrode, rendering the claim indefinite. Upon rejection of claim 22, all claims depending from claim 22 are also rejected.

15. Claim 22 recites the limitation "a second electrode" in line 2. Prior to this recitation, a second electrode has been introduced. It is unclear if the limitation refers to the second electrode previously introduced, or if the limitation intends to introduce another second electrode, rendering the claim indefinite. Upon rejection of claim 22, all claims depending from claim 22 are also rejected.

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. Claims 17-20, 23, 28 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Lum et al. (U.S. Patent Number 6,391,005).

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In regard to claims 17-20, 23, 28 and 29, Lum et al. disclose a device which determines a penetration depth of the object by sensing the impedance of the material penetrated. The device disclosed by Lum et al. is an apparatus which includes a shaft with penetrating tip, for penetration into an object. The Lum et al. apparatus further includes two conductors (120, 122) which act as two electrodes. The sensors are electrically wired, therefore there is a source of current which is supplied to the at least two electrodes during the operation of the device (col. 3, lines 11-27).

The electrodes are positioned on the penetration instrument for measuring impedance between the electrodes (col. 3, lines 11-53). The electrodes are arranged such that the first electrode has a contact surface coinciding with a distal surface of the penetration instrument and the second electrode has a contact surface coinciding with a lateral surface of the penetration instrument (Figure 2A).

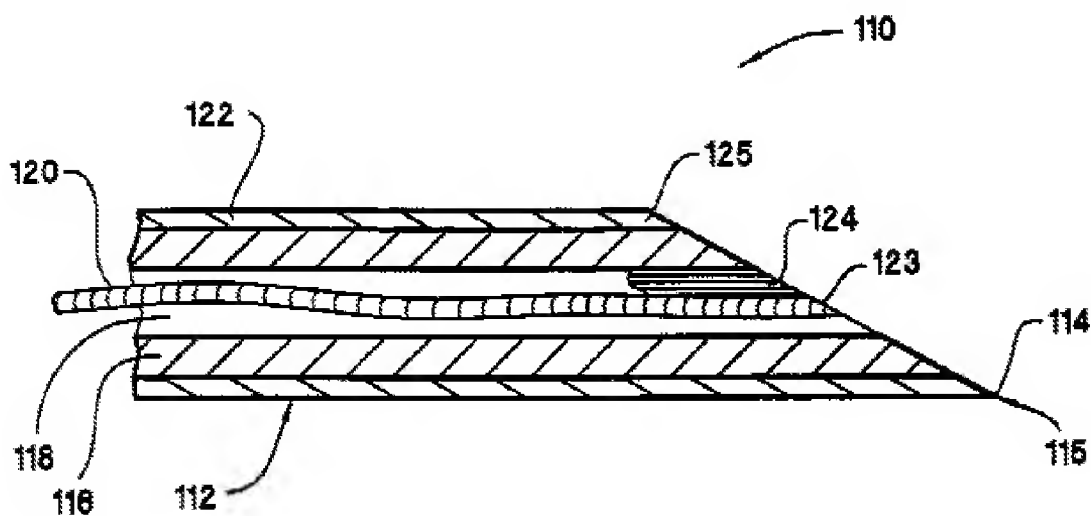
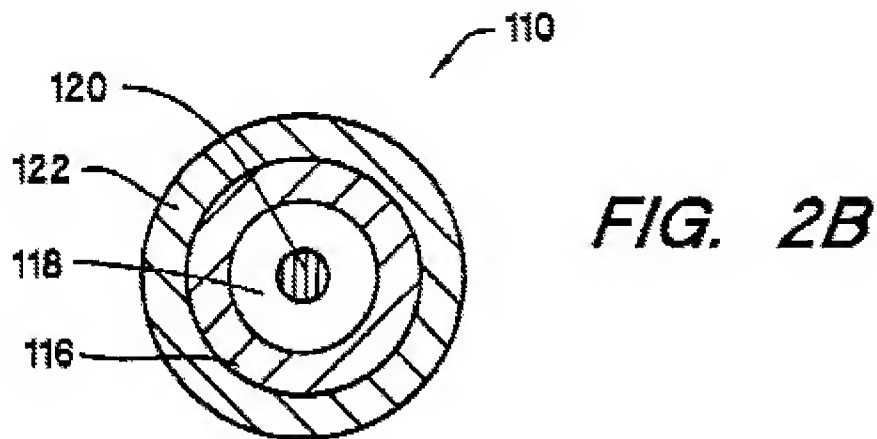


FIG. 2A

The contact surfaces of the device are positioned such that the degree of penetration can be

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determined. Lum et al. discuss various designs for the penetration instrument including having a constant contact surface which coincides with the degree of penetration of the penetration instrument in the anatomical structure. (col. 3, lines 59-67; col. 4, lines 1- 25). Figure 2B shows the two electrodes being symmetrically and coaxially arranged. This annular arrangement has the electrodes separated from each other by insulation (Figure 2B).



The device is designed to detect signals which are generated to measure the impedance variation and record the information during the analysis. Lum et al. disclose the device having an autonomous operating mechanism in which the device is designed to stop penetration upon reaching a predetermined depth or impedance measurement is reached. A central channel (138) is disposed within the device as described by Lum et al. This lumen is capable of being used to introduce another instrument to the target area.

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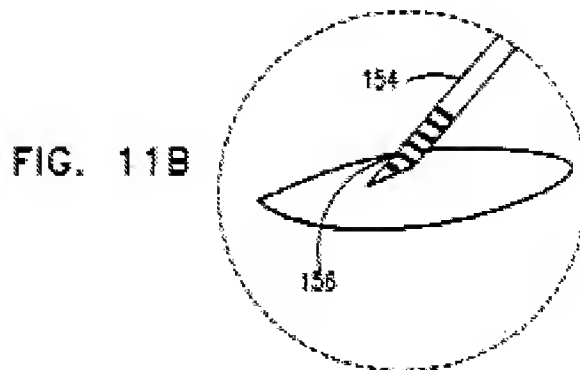
Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. Claims 21, 22 and 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lum et al. (U.S. Patent Number 6,391,005) in view of Pearlman (U.S. Patent Application Publication Number 2003/0105410).

In regard to claims 21, 22 and 24-27, Lum et al. disclose the features of the Applicant's invention as described above. Lum et al. do not specifically disclose having at least three electrodes. Pearlman et al. disclose an apparatus for aiding the identification of tissue type. The device disclosed by Pearlman includes a probe with electrodes for measuring the impedance of the tissue at a desired target site. The electrodes are annularly spaced on the probe creating a contact surface for the electrode which allows the impedance of the tissue at the target area to be determined (Figure 11B).



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It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a device which determines a penetration depth of the object by sensing the impedance of the material penetrated, similar to that disclosed by Lum et al., to include a plurality of secondary electrodes annularly spaced apart, similar to that disclosed by Pearlman, to distinguish the variation in impedance within tissue at a target site over a tissue area range (paragraph [0157]).

Additionally, in regard to claims 24-27, Lum et al. disclose the features of the Applicant's invention as described above. Lum et al. do not specifically disclose the device forming a sound upon reaching a desired impedance or a desired target area. Pearlman et al. disclose an apparatus for aiding the identification of tissue type. The device disclosed by Pearlman includes a probe with electrodes for measuring the impedance of the tissue at a desired target site. The device disclosed by Pearlman further includes a feature which produces an audible sound which is proportional to the impedance measured by the device (paragraph [0172]). Pearlman suggests the audible sound be a sound signal whose frequency is a function of the impedance measured, which is capable of either increasing or decreasing as a function of impedance. Other sound options disclosed by Pearlman include tones, beeps, clicks, etc. capable of indicating various activity of the device. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a device which determines a penetration depth of the object by sensing the impedance of the material penetrated, similar to that disclosed by Lum et al., to include an audible signal, similar to that disclosed by Pearlman, to assist with distinguishing the variation in impedance within tissue at a target site upon use of the device in locations of poor visibility.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fangemonique Smith whose telephone number is (571)272-8160. The examiner can normally be reached on Mon - Fri 8am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

FS

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736